Select Agents and Toxins Final Rule - Q and A's

1. What are the differences between the amended interim final rules and the final rules? Are there any major changes to the rules?

The final rules (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73) are being published in response to public comments received regarding the interim final rules and to harmonize the structure and format of the USDA regulations and the HHS regulations. For the most part, the regulations remain unchanged. The following outlines the most significant revisions:

- Provided clarification on what is meant by the term access as "an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin."
- Revised the genetic element section to include the regulation of nucleic acids that can produce infectious forms of any of the select agent viruses (e.g. genomes of positive strand RNA viruses on the select agent lists such as Eastern Equine Encephalitis virus, Venezuelan Equine Encephalitis virus, and Tick-borne encephalitis complex (flavi) viruses).
- Clarified that both registered and unregistered entities must report the identification of select agents and toxins presented for diagnosis, verification, or proficiency testing.
- Added a new requirement that entities that perform exempt activities of the identification of select agents and toxins presented for diagnosis, verification, or proficiency testing are now required, upon identification of the select agent or toxin, to secure such agent or toxin against theft, loss, or release during the period between identification and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported.
- Added language to clarify who would be deemed to own or control and, as such, would require a security risk assessment.
- Added a new requirement that drills or exercises of security, biosafety, and incident response plans must be conducted at least annually.
- A single form number will be used for each of the identical forms used by USDA and HHS. For example, "Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins," which was previously referenced as APHIS Form 2040 or CDC Form 0.1319, will now be referenced as APHIS/CDC Form 1).

2. Were there any changes made to the list of select agents or toxins in the final rules, compared to the amended interim final rules? (A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.)

- The list of USDA select agents and toxins has been changed to remove Newcastle disease virus (VVND), and add Newcastle disease virus (velogenic) in its place, to make it clear that we are regulating all of the velogenic strains.
- The USDA list of overlap select agents and toxins has been clarified by removing *Clostridium botulinum*, but continuing to list Botulinum neurotoxin producing species of *Clostridium*.

- The list of PPQ select agents and toxins has been changed to remove *Phakopsora pachyrhizi* and plum pox potyvirus from the list.
- The HHS and overlap select agents and toxins list remains unchanged. The list of the HHS and overlap select agents and toxins can be found at http://www.cdc.gov/od/sap.

3. Will my current certificate of registration remain valid once the final rule takes effect?

Yes, all registration certificates issued under the amended interim final rule will remain valid until the expiration date provided on the entity's certificate of registration.

4. I am currently registered under 7 C.F.R. Part 331, 9 C.F.R. Part 121, or 42 C.F.R. Part 73. Do I need to submit a new application or an amendment to my application as a result of updates to the final rule?

No, entities currently registered under 7 C.F.R. Part 331, 9 C.F.R. Part 121, or 42 C.F.R. Part 73 are not required to submit a new application when the Final Rule becomes effective. However, the Responsible Official should review all sections under the Final Rule to determine if any of the changes throughout the regulation dictate a modification to the information submitted to the USDA Secretary. The Responsible Official should immediately apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application to the USDA Secretary.

5. Will individuals have to undergo a new security risk assessment?

No. Security Risk Assessments (SRA) issued under the amended interim final rule will remain valid when the Final Rule becomes effective.

6. When does the Final Rule become effective?

The Final Rules become effective 30 days after publication in the Federal Register. Since it was published in the March 18, 2005 issue of the Federal Register, the Final Rule will become effective on April 17, 2005. An individual or entity must be in compliance with the provisions set forth in the regulation on the effective date as promulgated in the Final Rule.

7. Will my entity require a re-inspection as a result of the recently-published final rule?

No. Publication of the Final Rule does not require a re-inspection. However, without prior notification, program inspectors shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.